

FBI Laboratory Practices for Open Proficiency Testing

1 Purpose

The open proficiency testing practices are a measure used by the FBI Laboratory to monitor performance. These practices are designed to demonstrate that FBI Laboratory personnel performing forensic examinations or DNA databasing produce reliable work and that analytical procedures are conducted within the established performance criteria. The program is designed in a manner to monitor examiners, technicians, and the FBI Laboratory quality system. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

2 Scope

These practices apply to FBI Laboratory personnel who routinely perform analytical or interpretative procedures on evidentiary items and/or DNA database samples and who are required to participate in proficiency testing. Additionally, these practices apply to other personnel who remain qualified to support FBI Laboratory needs and are subsequently required to participate in proficiency testing. These practices also apply to the Proficiency Test Program Manager (PTPM) and to personnel responsible for various actions that occur as a result of proficiency testing. Open proficiency tests are analyzed and interpreted according to the approved technical procedures in use in each discipline and/or category of testing at the time of the proficiency test.

3 Practices

The PTPM manages the proficiency testing program to include liaising with FBI Laboratory personnel and the accrediting body regarding proficiency testing inconsistencies, where appropriate. When requested, generating proficiency test management reports from Forensic Advantage (FA) or requesting equivalent records from the DNA units.

3.1 Participation

3.1.1 Each examiner and technician in forensic science disciplines accredited to the ISO 17025 standard must complete at least one proficiency test annually to cover each category of testing appearing on the FBI Laboratory's Scope of Accreditation in which the examiner and/or technician routinely performs testing, except for latent print processing. A single proficiency test may cover more than one category of testing. Each DNA examiner and technician, individually or together, must complete two DNA external proficiency tests per year. Examiners involved in latent print processing will complete at least one processing proficiency test per accreditation cycle. Each examiner and technician engaged in testing activities in caseworking units that are

not accredited must successfully complete at least one proficiency test per calendar year in his/her category of testing. The proficiency test(s) may be external or internal; however, all examiners and technicians will participate in external proficiency tests where available and appropriate for the testing conducted in the FBI Laboratory. Refer to section 3.4 for information on internal proficiency tests. Each person tested must participate in the test to the extent they would perform the procedures in casework or DNA databasing.

3.1.1.1 When an examiner will remain proficient in the entire examination or DNA databasing process, an independent proficiency test must be completed. If the examiner is also participating in an examiner/technician test in the same proficiency test series, the examiner will not begin the assigned portion of the examiner/technician test until after the examiner's independent test is completed.

3.1.1.2 Any person who prepares an internal proficiency test and is required to complete a proficiency test must take an external proficiency test or an internal test prepared by another person.

3.1.1.3 Personnel who leave a position in a discipline and/or category(ies) of testing may continue to participate in proficiency testing for up to one year. The appropriate Technical Leader will determine the duration (not to exceed one year) in which the person will continue to participate in proficiency testing. The Technical Leader will ensure an Electronic Communication (EC) is serialized in Sentinel recording the duration. The EC will be approved, at a minimum, by the appropriate Technical Leader and affected Unit Chief(s). The proficiency testing plan will be modified as needed.

3.1.2 Approved Proficiency Tests

3.1.2.1 Proficiency tests will be approved by the appropriate Technical Leader and the Quality Manager. The appropriate Technical Leader will evaluate the technical merits of a test to ensure it is appropriate for the testing conducted in the discipline and/or category of testing within the FBI Laboratory. The Quality Manager will determine if a test meets accreditation requirements and/or the quality system requirements of the FBI Laboratory.

3.1.2.2 The PTPM will maintain a list of approved external proficiency tests. The Proficiency Test Representative (PTR) will ensure approved external proficiency tests are purchased. An unapproved test may be purchased for evaluation purposes.

3.1.2.3 If an approved external proficiency test is not available; an internally designed and prepared test will meet the annual proficiency testing requirement. Refer to section 3.4.

3.1.3 Proficiency Test Ordering and Plan

3.1.3.1 The PTR will arrange for the procurement of the necessary external proficiency tests. The procurement records will be retained by the PTR.

3.1.3.2 Each PTR will ensure the proficiency testing plan through the next full reassessment is recorded. This plan will be updated by December 31st of each year. This schedule will be maintained on the Proficiency Testing SharePoint site and include the following:

- Location(s) where test will be performed (if different from participant's assigned duty station)
- Unit
- Participant
- Discipline and Category(ies) of Testing
- Proficiency Test
- Proficiency Test Type
- Estimated Distribution Date

3.1.3.3 Each PTR will ensure the plan includes a representative sample of the components/parameters and equipment/technologies within each applicable discipline listed on the scope of accreditation.

3.2 Proficiency Test Procedures

A level 2 document will contain procedures for internal and/or external proficiency testing. These procedures will contain a program scope and a description of the proficiency test evaluation process. If a proficiency test evaluation form is used, the form and its use will be included in the relevant proficiency test procedure(s). Participants will follow appropriate technical procedures when participating in proficiency tests. The results (with the exception of DNA proficiency tests) will be uploaded into the Case Record Object Repository in FA; proficiency test evaluations will be entered into FA. DNA units will have procedures for recording the results and evaluations.

3.2.1 Program Scope

This statement will include a reference to the positions and categories of testing to which the program applies and whether the program includes internal and/or external proficiency tests.

3.2.2 Sample Retention

Proficiency test samples must be retained through the evaluation of a proficiency test and, when applicable, the resolution of corrective actions associated with that proficiency test.

3.3 External Proficiency Testing

The PTR will ensure proficiency tests are accounted for, distributed, submitted by the provider's due date, evaluated, and recorded.

3.3.1 Date Assigned

The date assigned identifies the day on which the test participant was assigned a proficiency test. This date identifies the calendar year for which the test will be credited. For example, if the date assigned for a test is December 18, 2020, and the due date for that test is January 18, 2021, the test participant is credited with participating in a 2020 proficiency test. The PTR will ensure the timely issuance of external tests. The date the proficiency test is assigned will be recorded in FA. DNA units will have procedures for recording the date assigned.

3.3.2 Internal Evaluation of External Proficiency Test for Current Cycle

Proficiency test results not accepted by the provider do not satisfy the external proficiency test requirement for that category of testing for the calendar year in which it was assigned. With the exception of DNA, the test may be evaluated internally for the current proficiency test cycle. If this occurs, the affected Unit Chief and/or PTR will establish a new internal due date for the proficiency test(s) to be evaluated internally. This due date must precede the release of any manufacturer's information, individual reports, and/or summary reports released by the external test provider.

3.3.3 Preparation of Test Provider Data Forms

Results for external proficiency tests will be recorded on external provider data forms according to instructions provided by the external provider. Attachments may be used to supplement the data forms but cannot be used in lieu of completing the data forms.

3.3.4 Verification of Identification or Association and Technical Review

Proficiency test identifications or associations will be verified, when appropriate, and all proficiency tests will be technically reviewed using the same procedures used for casework. The verification and/or technical review will be recorded in FA except for DNA. DNA databasing will have procedures for the technical review of proficiency tests. The verification and/or technical review of DNA proficiency tests will be recorded according to DNA proficiency testing procedures.

3.3.4.1 If a person who will verify and/or technically review a proficiency test is participating in the same test distribution, the PTR will ensure the person has finished their portion of the test prior to performing a verification or technical review.

3.3.4.2 If the PTR is participating in the test distribution and will be submitting other participants' results to the provider, the Unit Chief will ensure the PTR has finished their portion of the test prior to submitting results.

3.3.4.3 Analytical/interpretive inconsistencies will be handled according to section 3.5.3.2.

3.3.5 Administrative Review

All proficiency tests will be administratively reviewed. An administrative review will not be conducted by the participant whose data sheets/results are being reviewed. A level 2 document may further define requirements for an administrative reviewer. Completed external provider data sheets will be included in the administrative review process. The administrative review will be conducted before the proficiency tests results are submitted to the provider or internal evaluator. The administrative review will be recorded in FA except for DNA. DNA databasing will have procedures for the administrative review of proficiency tests. The administrative review of DNA proficiency tests will be recorded according to DNA proficiency testing procedures.

3.3.5.1 If the administrative reviewer is participating in the same test distribution; the PTR will ensure the reviewer has finished their portion of the test prior to performing the review.

3.3.5.2 Administrative errors will be handled according to section 3.5.3.1.

3.3.6 Submitting Test Results

3.3.6.1 Technical and administrative reviews must be completed prior to submitting test results.

3.3.6.2 The PTR will ensure the electronic data sheets, web-based data entry forms, or physical forms are submitted according to the provider's instructions by the provider's due date, and that the results are authorized for release to the accrediting body.

3.3.6.3 After the results have been submitted to the test provider, proficiency testing records and completed provider data sheets are considered final and cannot be changed.

3.3.7 If a problem that may impact the quality of the original test samples received from an external test provider is identified, the affected PTR will notify the PTPM in writing regarding the nature of the problem.

3.4 Internal Proficiency Testing

If a proficiency testing program includes internal proficiency testing, a level 2 document will address test design, sample preparation, and test preparation. If a retained external proficiency test will be used as an internal proficiency test, refer to section 3.4.3.5.

Those categories of testing unable to comply with the requirements listed below will record a course of action. The affected Unit Chief(s), appropriate Technical Leader, PTR(s), and Quality Manager will agree on the course of action to be taken to ensure the quality of the proficiency testing.

3.4.1 Internal Test Design

An internal proficiency test design will include:

- the objective of each test or batch of tests.
- what the test is designed to measure.
- the expected outcome, including the acceptable limits, when appropriate.
- how the test will be prepared, to include sufficient detail to replicate the test.

3.4.1.1 The design of a proficiency test(s) must be approved by the Technical Leader. This approval will be recorded. The approved design will be provided to the PTR.

3.4.1.2 The PTR will forward the approved design to the PTPM. The proficiency test design will be administratively reviewed by the PTPM for appropriateness and completeness of each design relative to quality assurance. The PTPM will record the review.

3.4.2 Internal Sample Preparation to be Used in an Internal Proficiency Test

Proficiency test samples will be prepared using specimens, materials, and methods that ensure their uniformity, identity, and integrity. Prior to a person other than an examiner or technician in the category of testing participating in the preparation of samples, the name and qualifications of the candidate will be submitted to the Technical Leader for approval. If approval is not granted by the Technical Leader, another candidate will be chosen. At a minimum, the following will be identified when preparing a proficiency test sample.

- Types of samples that need to be prepared and the materials necessary for their preparation.
- Steps taken to collect or prepare a sample.
- Who collected or prepared the sample.
- When the sample was collected or prepared.

3.4.2.1 Quality control measures address the verification of the accuracy and integrity of each proficiency test sample. At a minimum, these measures will include:

- Labeling each sample with a unique identifier.
- Recording the source from which the sample was collected. The level of detail for the source identification may differ for each category of testing.
- Verifying the sample identifier for accuracy. This verification of accuracy will be recorded and conducted by another person.
- Preparing each sample that produces qualitative results in such a way that it contains sufficient class and/or individual characteristics for meaningful analysis and/or comparison.
- Preparing each sample that produces quantitative results in such a way that it will contain an amount of analyte sufficient to enable a conclusion to be drawn from the results of the analysis and/or comparison.
- Validating each sample (or lot of samples) for desired qualitative or quantitative results. The validation will be conducted by an examiner or

technician qualified in the category of testing or by a person who approved by the Technical Leader. This validation must be recorded.

3.4.2.2 Samples must be appropriately labeled as proficiency test samples.

3.4.3 Internal Test Preparation

Each internal proficiency test will be prepared by a person determined by the Technical Leader to possess sufficient knowledge of and/or experience in the category of testing for which the test is being prepared. The preparer will use the proficiency test samples that were prepared according to section 3.4.2 to create the internal proficiency test. At a minimum, the name of the person who prepared the test and when the test was prepared will be recorded.

3.4.3.1 Quality control measures ensure the accuracy of information contained in each internal proficiency test. At a minimum, these measures will include:

- Labeling each test with a unique identifier.
- Recording all samples and sample identifiers used for each test.
- Verifying the sample and test identifiers for accuracy. This verification of accuracy will be recorded and conducted by another person.
- Validating each test (or lot of tests) to ensure the expected results can be obtained. This validation will be conducted by an examiner or technician, as appropriate, qualified in the category of testing or by a person approved by the Technical Leader. This validation must be recorded. An examiner/technician who validates the results may count this validation as an internal proficiency test for that category of testing, with the requirement that they do not have direct knowledge of the preparation of the samples or the test. Verification of identification or association and technical review will be required for this instance. The person who validated the test preparation may conduct the verification of any identification or association and/or the technical review of other tests of this lot.

3.4.3.2 Expected results of each internal proficiency test will be recorded, including acceptable limits, when appropriate.

3.4.3.3 Appropriate controls among the samples submitted for each internal proficiency test will be used, where appropriate or necessary. Reference materials may be used as part of the control system (if available) for a particular examination or test.

3.4.3.4 An additional internal proficiency test sample(s) from the same source for possible re-analysis and comparison, must be retained through the evaluation of a proficiency test and, when applicable, the resolution of corrective actions associated with that proficiency test.

3.4.3.5 External Proficiency Test Samples Used in Internal Test Preparation

3.4.3.5.1 Retained external proficiency test samples may be used in the preparation of an internal proficiency test or a requalification test.

3.4.3.5.2 Each test will be prepared by a person determined by the Technical Leader to possess sufficient knowledge of and/or experience in the category of testing for which the test is being prepared.

3.4.3.5.3 The following will be recorded when preparing a test using retained external proficiency test samples:

- Who prepared the test.
- When the test was prepared.
- The unique identifier for the test.
- Sample(s) and sample identifier(s) used for the test.

3.4.3.5.4 When retained external proficiency test samples are used, the PTR must ensure the sample(s)/test identification is altered such that the test participant cannot correlate any published results with the proficiency test sample(s).

3.4.3.5.5 The sample's new identifier must be recorded and traceable to the test provider's sample/test identifiers. The retained external proficiency test sample identifier and the sample's new identifier must be verified. This verification of accuracy will be conducted and recorded by another person for all samples used in the test.

3.4.3.5.6 The expected results for retained external proficiency test samples do not need to be validated or verified. The manufacturer's information for the retained external proficiency test samples will be considered the expected results.

3.4.4 Internal Test Administration

3.4.4.1 Date Assigned

The date assigned identifies the day on which the test participant was assigned a proficiency test. This date identifies the calendar year for which the test will be credited. For example, if the date assigned for a test is December 18, 2020, and the due date for that test is January 18, 2021, the test participant is credited with participating in a 2020 proficiency test. The PTR will ensure the timely issuance of internal tests. The date the proficiency test is assigned will be recorded in FA.

3.4.4.2 Due Date

The Unit Chief and/or PTR will establish the internal proficiency test due date. If a test is not completed and returned by the due date, that test does not satisfy the proficiency testing requirement for the category of testing for the calendar year in which it was assigned.

3.4.5 Proficiency Results Form

Results for all internal tests will be recorded in FA and may additionally be recorded on a proficiency results form. If used, the form will be uploaded into the Case Record Object Repository in FA. The proficiency results form will include at a minimum:

- Name(s) of test participant(s).
- Test type (position type and internal/external).
- Test identification number.
- Completion date.
- Test results including conclusions, where applicable.
- Records of technical and administrative reviews.

3.4.6 Verification of Identification or Association, Technical Review, and Administrative Review

Verification of identification or association, technical review, and administrative review will be performed according to sections 3.3.4 and 3.3.5.

3.5 Evaluation of Proficiency Test Results

3.5.1 The PTR will obtain and review the proficiency test manufacturer's information report (when provided), individual reports, and summary reports. The PTR will evaluate the submitted results and supporting records to compare those results with the above reports. The PTR will also review the proficiency test manufacturer's information report (when provided), individual reports, and summary reports and their evaluation of the submitted results with the affected Unit Chief and/or Technical Leader.

3.5.1.1 The PTR will ensure the manufacturer's information report (when provided), individual reports, and summary reports are available to the test participant(s) for review.

3.5.1.2 The PTR will ensure the following information is recorded in FA and when applicable, recorded on a unit evaluation form:

- Name(s) of test participant(s).
- Test type (position type and internal/external).
- Test identification number.
- Date assigned.
- Date returned.
- Due date.
- Evaluation date.
- Name of evaluator.
- Results: satisfactory or unsatisfactory.
- Description of discrepancy, when appropriate.

DNA will have procedures for recording the above information.

3.5.1.3 The proficiency test evaluation will be completed within 20 calendar days after the individual and/or summary reports are received for an external test.

3.5.1.4 The PTR will ensure the completion of the evaluation, the appropriate evaluation term (i.e., satisfactory, unsatisfactory, or discontinued), and the test participant's feedback date are entered into FA contemporaneously with the evaluation and feedback. The feedback date is the date the evaluation was reviewed by the test participant. DNA will have procedures for recording this information.

3.5.1.5 If a proficiency test evaluation form is used; it will be made available to the test participant. Each test participant must record receipt of the test evaluation. These records include the name of the test participant, the initials or signature of the test participant, and the date the evaluation was reviewed. If used, the form will be uploaded into the Case Record Object Repository in FA. For DNA proficiency tests, the unit evaluation form will be maintained with the proficiency test records.

3.5.1.6 The PTR will ensure that the evaluation of internal proficiency tests is conducted within 20 calendar days from the administrative review.

3.5.2 Notification of Inconsistency

The PTR, affected Unit Chief, or Technical Leader will notify the PTPM in writing, at the time of detection, of any potential analytical/interpretative proficiency test inconsistency.

3.5.3 Nonconformities

3.5.3.1 Administrative Errors Identified by Laboratory Personnel

3.5.3.1.1 Notification of Administrative Errors

If an administrative error is detected it will be brought directly to the attention of the test participant.

3.5.3.1.2 Action Taken

All administrative errors detected during an administrative review will be corrected prior to the administrative review being completed. If the administrative error is detected during the evaluation of the results by the PTR, it will be corrected. The PTR will ensure any corrected data sheet(s) and examination notes or DNA database notes are maintained with the proficiency test records. The PTPM will be notified in writing if the correction requires communication with the provider.

3.5.3.2 Potential Analytical/Interpretative Inconsistencies Identified Prior to Submission

3.5.3.2.1 Notification of Analytical/Interpretative Inconsistencies

If a potential inconsistency is detected during a verification or technical review, the nature of the potential inconsistency will be brought to the attention of the Unit Chief and Technical Leader. The Technical Leader will initiate the appropriate evaluation of any analytical/interpretative inconsistency and will determine whether the potential inconsistency is an analytical/interpretative inconsistency. The Technical Leader will notify the PTR, the appropriate Unit Chief(s), and PTPM in writing of the evaluation and resulting determination.

3.5.3.2.2 Action Taken

If the inconsistency is detected during a verification/technical review, at the discretion of the Technical Leader, the test participant may address the inconsistency and complete the proficiency test.

3.5.3.2.2.1 If necessary, the Technical Leader will initiate a corrective action according to the LOM – Practices for Addressing a Nonconformity to address the inconsistency. The Unit Chief and Technical Leader may have the item(s) re-examined and reviewed by examiners other than the original examiner and technical reviewer. The Unit Chief and Technical Leader will record the inconsistency and notify the affected test participant.

3.5.3.2.2.2 The examiner and/or technician will not conduct examinations or DNA databasing or issue *Laboratory Reports* (7-1, 7-1 LIMS) or *DNA Match Confirmation Letters* until the appropriate corrective action steps have been completed and the examiner and/or technician is authorized to resume examinations or DNA databasing by the Unit Chief and Technical Leader.

3.5.3.2.2.3 The Unit Chief will ensure casework or DNA databasing records from the examiner and/or technician are reviewed to ensure the examinations or DNA databasing have been conducted properly, the notes and results have been reviewed, and the appropriate conclusions have been rendered. The review of casework or DNA database records will include all cases or DNA database samples that were completed since the last satisfactory proficiency test in that category of testing and are relevant to the inconsistency and/or the design of the proficiency test.

3.5.3.2.2.4 The examiner and/or technician will complete remedial training and a requalification test in the category of testing in which the inconsistency occurred.

3.5.3.3 Potential Inconsistencies Identified by the PTR

If a potential inconsistency is identified by the PTR after the initial assessment of external proficiency test results against the manufacturer's information, individual reports, and/or the summary reports, the affected Unit Chief and Technical Leader will be notified of the potential inconsistency in writing. The Unit Chief and Technical Leader will determine whether the potential inconsistency is an acceptable result or is an inconsistency that is administrative or

analytical/interpretive in nature and will notify the PTPM of the type of inconsistency in writing. If it is determined to be an analytical/interpretive inconsistency, the Unit Chief and Technical Leader will follow the steps listed in sections 3.5.3.2 through 3.5.3.2.2.4.

3.5.3.4 Potential Inconsistencies Identified by a Proficiency Test Provider

3.5.3.4.1 Notification of Potential Inconsistencies or Non-Consensus Results

If a potential inconsistency or non-consensus result is identified by a proficiency test provider, the PTR will notify the affected Unit Chief, Technical Leader, and the PTPM in writing. The Unit Chief or Technical Leader will notify the affected test participant.

3.5.3.4.2 Action Taken

The Unit Chief and Technical Leader will review the potential inconsistency or non-consensus result noted by the proficiency test provider and the examination notes of the affected test participant to determine whether the potential inconsistency or non-consensus result is an acceptable result or is an inconsistency that is administrative or analytical/interpretive in nature.

3.5.3.4.2.1 If the potential inconsistency or non-consensus result is determined to be an acceptable result; the Unit Chief or Technical Leader will communicate this to the PTR and PTPM in writing.

3.5.3.4.2.2 If the inconsistency or non-consensus result is determined to be an administrative error; it will be corrected by the test participant. The Unit Chief or Technical Leader will communicate in writing the resolution of the administrative error to the PTR and PTPM. The PTR will ensure any corrected data sheet(s) and testing notes are maintained with the proficiency test records.

3.5.3.4.2.3 If the inconsistency or non-consensus result is determined to be an analytical/interpretive error, the Unit Chief or Technical Leader will communicate in writing to the PTR and the PTPM the resolution of the analytical/interpretative error or non-consensus result including a copy of any corrective action(s), if necessary. Additionally, the PTR will ensure a copy of the affected test participant's testing notes, including the resulting conclusions for the proficiency test records, is maintained with the proficiency test records.

3.5.3.5 Accrediting Body Communications

3.5.3.5.1 At times, the accrediting body and the FBI Laboratory may need to communicate regarding proficiency tests. The PTR will notify the affected Unit Chief, Technical Leader, and PTPM in writing and will forward to the PTPM any communications from the accrediting body for review. The Unit Chief or Technical Leader will provide a written response to the PTR and PTPM regarding the accrediting body communication by the date specified in the accompanying notification.

3.5.3.5.2 When a potential inconsistency or non-consensus result has been identified by the FBI Laboratory; the FBI Laboratory may proactively communicate with the accrediting body regarding the potential inconsistency. The PTR will notify the affected Unit Chief, Technical Leader, and PTPM in writing and will forward any information to be included in the proactive communications to the PTPM.

3.6 Extended Leave

3.6.1 When a person is on extended leave; the Unit Chief and Technical Leader will ensure that person is administered a requalification test(s) upon return from leave to ensure continued proficiency. Successful completion of the requalification test(s) must be accomplished and recorded prior to resuming independent casework or DNA databasing responsibilities.

3.6.2 The length of leave considered to be “extended leave” will be at the discretion of the Technical Leader. However, any leave exceeding one half of an annual proficiency test cycle will be considered “extended leave.” In the DNA units, leave that takes a person out of the semi-annual proficiency test cycle will be considered “extended leave.”

3.6.3 Retained external proficiency test samples may be used in the preparation of a requalification test(s) to meet this requirement. If retained external proficiency test samples are used, refer to section 3.4.3.5.

4 Records

Each Unit Chief will ensure all proficiency test-related records are permanently retained in FA and/or the unit to which the participant is assigned.

- 4.1** The following information must be retained for all proficiency tests:
- Distribution records.
 - Examination or DNA database records.
 - External test provider data sheets or proficiency results form for internal tests.
 - Test information for external tests to include test manufacturer/provider, test identifier, participant code, test type, and category of testing.
 - Date assigned.
 - Due date.
 - Examinations completed date.
 - Evaluation date.
 - Feedback date.
 - Completed date.
 - Evaluation records including completed evaluation forms, if used.
 - Corrective action records, if applicable.
 - Accrediting body communications, if applicable.
 - Location(s) where test performed (if different from participant’s assigned duty station).

4.2 The following information must be retained for internally prepared tests:

The records to be retained for sample preparation include:

- The unique identifier for the sample.
- Who prepared the sample.
- When the sample was prepared.
- The source of each sample.
- Who witnessed the source and sample identification accuracy.
- Who validated the quantitative and/or qualitative results.

The records to be retained for test preparation include:

- The unique identifier for the test.
- Who prepared the test.
- When the test was prepared.
- What samples are included in each test (by sample identifier).
- Who verified the sample and test identification accuracy.
- The expected results, including acceptable limits (when appropriate), of the test.
- Who validated the expected results of the test.

4.3 The following proficiency test records will be maintained by the Forensic Analysis Support Unit through one accreditation cycle.

- List of approved external proficiency tests.
- Proficiency testing plan(s).
- Proficiency test schedule.
- Corrective action records, if applicable.
- Accrediting body communications, when received.

4.4 Procurement records related to proficiency tests will be retained by units ordering external proficiency tests through one accreditation cycle.

4.5 Requalification records will be maintained in the person's unit or applicable support unit.

5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

FBI Laboratory Operations Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration

Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Quality Assurance Standards for Forensic DNA Testing Laboratories, Federal Bureau of Investigation, July 1, 2020.

Quality Assurance Standards for DNA Databasing Laboratories, Federal Bureau of Investigation, July 1, 2020.

Rev. #	Issue Date	History
13	06/03/19	Added requirements regarding personnel who leave a position in section 3.1.1.3. Updated the list in section 3.1.3.2 to include location and discipline. Added section 3.1.3.3 to require a proficiency testing plan(s). In section 3.3.4.2 added a requirement to cover instances when the PTR is participating in the test. Expanded section 3.3.6.2 to include release to accrediting body. Added reference to nonconformity practice in section 3.5.3.2.2.1. In section 3.6.1, clarified that requalification must be recorded. Listed additional records in section 4 that correspond to revised content. Updated list of references in section 5.
14	12/21/20	Minor typos and edits throughout for clarity. 1 - updated test to monitor 2 - SOPs to technical procedures and throughout document 3.1.1.3 and 3.1.3.2 - schedule to plan 3.1.3.2 - clarified plan required through full assessment 3.1.3.3 - Each PTR will ensure plan includes representative sample of the components/parameters and equipment/technologies within each applicable discipline listed on the scope of accreditation 3.3.1 and throughout document clarified where DNA will have procedures or handled differently 3.3.3 - sheets to forms and removed information related to former hardcopy submission of results 3.5.3.2.2.2 - removed reference to TEDAC Laboratory Report (7-273) 3.5.3.4 and throughout document - removed references and requirements related to PRC 5 – added LOM and updated DNA QAS revision date

Approval

Redacted - Signatures on File

Laboratory Director

Date: 12/18/2020

Quality Manager

Date: 12/18/2020